

data: Coverage with Evidence Development (CED). The objective of this study was to review the outcomes of the CEDs granted by TLV during the years 2005 to 2012, and to appreciate if it is an effective way to manage uncertainty. **METHODS:** All decisions published from January 2005 to December 2012 on the TLV website were screened. All decisions that included a CED were reviewed and the information on the initial decision for a CED and the final decision based on the evidence developed were extracted in a standardized way. The information was then analyzed. **RESULTS:** During the period TLV issued 38 decisions with a CED, 4 in 2012, 5 in 2011, 11 in 2010, 3 in 2009, 2 in 2008, 8 in 2007, 5 in 2006 and none in 2005. For 10 CEDs issued 2010 to 2012 the time for evaluation had to yet been reached. For 12 CED decision taken from 2006 to 2010 the time for evaluation was reached but no decision had been taken and the products continue to be reimbursed according to the conditions in the temporary reimbursement decision. 7 products were granted general reimbursement and 9 limited reimbursement based on the evaluation of the evidence. No product was rejected reimbursement. **CONCLUSIONS:** Although it is early to draw any final conclusions, a significant number of CED decisions were not followed up with a final decision, which leads to continued reimbursement. The risk of de-reimbursement based on a CED seems minimal in Sweden. Therefore it is unclear if CED will actually contribute to manage uncertainty in Sweden.

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VARIANCES IN INDIVIDUALS' PRESCRIPTION DRUG COSTS IN IRELAND

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OBJECTIVES: To assess the average individual's drug costs prescribed under the main community drug scheme in Ireland over time, by age cohort and by geographical region. It also examined regional costs having standardized for age and sex. **METHODS:** The 2002 to 2012 average pharmacy payment per eligible person, number of items prescribed per person and the average cost per item prescribed were calculated. The most recent average individual cost of medicines was examined for each of the 4 health regions and 32 sub-regions by 22 age and sex cohorts. Regional age and sex adjustments were made by applying the scheme's national age and sex weights to each region's costs. This produced regional cost estimates independent of age and sex variations. **RESULTS:** Community drug expenditure has undergone substantial growth in the past 10 years with costs more than doubling and the number of persons covered by the main scheme increasing by nearly 60%. Nationally an individual's average cost of medicines was €713 in 2011, varying from €670 (-6%) in HSE-West to €762 (+7%) in HSE-South. Sub-regional LHO (local health office) cost variances were significantly greater ranging from €200 to €1,200. Average cost increases with age and for persons over 75 was nearly 4 times those aged 35 to 44 (€1,689 versus €446). Removing the impact of age and sex increases cost variances marginally overall, restraining some regions costs and promoting others. **CONCLUSIONS:** Individuals' prescription drug costs vary significantly by age and sex however regional cost differences are not explained by variances in age and sex and may be a result of other factors such as prevalence of chronic health conditions and GP prescribing patterns.

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ANALYSIS AND CLASSIFICATION OF RISK-SHARING SCHEMES PROPOSED IN REIMBURSEMENT APPLICATION RECEIVED BY AHTAPOL IN 2012

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OBJECTIVES: To analyze and classify the Risk-Sharing Schemes (RSSs) proposed in reimbursement applications received by Agency for Health Technology Assessment in Poland (AHTAPol) in 2012. **METHODS:** Risk-Sharing Schemes proposed in reimbursement applications received by AHTAPol in 2012 were quantitatively and qualitatively analyzed. The classification of the RSSs was also conducted based on both Carlson's approach and the Polish Act on Reimbursement of medicinal products. **RESULTS:** In the studied period, 52 reimbursement applications with 26 proposed RSSs were received by AHTAPol. They were classified into 5 categories according to the Act on Reimbursement. The most common category was making the official sales price dependent on the applicant providing supplies at a reduced price, as specified in the negotiations on the price of the medicine (34.61%). Further categories were: making the official sales price dependent on a pay-back of a part of the reimbursement obtained to the entity which is obliged to finance benefits with public funds (23.08%), making the official sales price dependent on the level of turnover of the medicine (11.54%) and making the level of the applicant's revenues dependent on the health effects achieved (3.85%). RSSs classified as others constituted 26.92% of all. Among 26 proposed RSSs only 8 of them could be classified according to the Carlson's approach (1 proposition included more than one category). As a results, 4 Price Volume Agreements, 4 Manufacturer Funded Treatment Initiation and 1 Conditional Treatment Continuation were identified. **CONCLUSIONS:** Most of the propositions should not be considered as RSS according to the Carlson's approach. The most common propositions were related to medicinal product's price reduction and did not include any risk sharing. There is a strong need for further research.

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RISK SHARING FOR INNOVATIVE PHARMACEUTICALS WITHIN SOCIAL HEALTH INSURANCE: EXPERIENCES FROM CHINA

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OBJECTIVES: To understand current risk sharing scheme landscape for innovative pharmaceuticals in some typical provinces and cities of China. **METHODS:** Risk sharing schemes for pharmaceuticals in four provinces (Guangdong, Zhejiang, Jiangsu and Sichuan) and three cities (Guangzhou, Hangzhou and Chengdu) were

systematically collected through visiting social health insurance bureau websites, literature review and key informant interview. Case study and comparison analysis were conducted among these schemes. **RESULTS:** Two kinds of risk sharing schemes, performance based scheme and financial based scheme, were employed in sampling provinces and cities, with the latter model more often implemented. Performance based scheme has only been developed in one city (Guangzhou) for a non-small-cell lung cancer drug. Patients eligible for inclusion criteria and treated in one of three designated hospitals could be qualified to reimburse for more than one year treatment if they were responsive to the drug. Other provinces and cities has adopted the financial based scheme, mainly focusing on increasing patients access to expensive drugs, usually for breast cancer, leukemia and non-small-cell lung cancer and not covered by health insurance schemes. For instance, local health insurance fund of Zhejiang and Jiangsu province would only reimburse patients' five to six months treatment and pharmaceutical company should sponsor patients' treatment for the next six months. Besides, cities like Qingdao and Chengdu implemented the price volume scheme for special drugs and medical materials in order to control fund expenditure. **CONCLUSIONS:** By risk sharing scheme, some innovative drugs, previously not covered by social health insurance, can be reimbursed, which will increase patients' access, reduce patients economic burden, and help expanding pharmaceutical companies' market share. However, as risk sharing scheme in China has only been adopted for only one or two years, long-term impact still needs to be observed and evaluated.

PHP210

SQUARING THE CIRCLE: INNOVATIVE CONTRACTING TO ACHIEVE MARKET ACCESS FOR INNOVATIVE PRODUCTS

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In an increasingly resource-constrained environment, a variety of innovative contracting arrangements exist, representing an alternative to conventional pricing and reimbursement agreements between payer and manufacturer. There are various tools and resources that may influence funding with which payers and prescribers would welcome support from manufacturers. **OBJECTIVES:** To gain an overview of contractual agreements currently used within the pharmaceutical sector and to uncover how innovative contracting has, and continues to, evolve. **METHODS:** Secondary research was conducted to identify examples of innovative contracting, highlighting elements that work and associated hurdles, in order to understand issues relating to transparency and implementation. **RESULTS:** Sixteen markets worldwide embrace innovative schemes with a further 5 markets beginning to show uptake. In the past, agreements were predominantly performance-based. However, companies are increasingly moving towards financial schemes such as product bundling, confidential discounts and fixed price treatments. The most common elements of risk-sharing agreements are price volume agreements (39%), requirement for data collection (29.5%), and access limited only to eligible patients (13.1%). Innovative contracts are predominantly used for drugs that relate to high cost or high performance with oncology being the therapeutic area that dominates these agreements. **CONCLUSIONS:** Innovative contracting schemes can aid manufacturers with market access, help to maintain price and increase usage. However, the current design of many agreements is suboptimal, and there are hurdles which need to be overcome. It is important that there is a balance between risk and incentive for all stakeholders, and this balance between the benefits and cost implications must be carefully considered.

HEALTH CARE USE & POLICY STUDIES – Conceptual Papers

PHP211

THE HEALTH OF HEALTH TECHNOLOGY ASSESSMENT IN IRELAND: FIVE POINTS FOR IMPROVEMENT

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This study critically appraises the contribution of cost-effectiveness analysis (CEA) in improving the rational allocation of health care resources in Ireland. While Ireland has successfully established some of the institutional infrastructure for CEA, there remain key areas for improvement: 1) Ireland has an explicit cost-effectiveness threshold of €45,000/QALY. It resulted from negotiations between the pharmaceutical industry and the public health service and only applies to pharmaceutical interventions. If Ireland is to use a threshold, it would be better served by an empirically determined threshold that applies to all interventions. 2) The threshold has recently been exceeded by a number of expensive drugs, in some cases by a very large margin. Conversely, despite being highly cost-effective, colorectal screening remains unimplemented due to a failure to allocate resources. In the absence of clarity around these decisions, the allocations appear to indicate that considerations of budget impact are dominating rather than complementing those of cost-effectiveness. 3) Recent CEAs by Ireland's statutory health technology assessment authority, the Health Information and Quality Authority (HIQA), appear to confuse average cost-effectiveness ratios with incremental cost-effectiveness ratios (ICERs). Clarity around the interpretation of cost-effectiveness evidence is required to instil confidence in the process. 4) Ireland has an established CEA process to appraise new drugs. However, this process has been bypassed in recent cases, as some costly cancer drugs have been approved before being subject to CEA, despite recommendations that these drugs be assessed. Consistency in approach is required to instil confidence in the process. 5) Greater transparency around reimbursement decisions would be desirable, whereby the relevant bodies issue documentation explaining their decisions and deliberations. In conclusion, CEA could make a greater contribution to rational resource allocation in Ireland if more rigorous and consistent decision rules were applied. Greater accountability of the decision making process should further that goal.